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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,360	12/21/2001	Eugene H. Gans	01-40326-US	6447

7590 12/03/2003

William J. McNichol, Jr., Esquire
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/037,360	GANS ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 13-60* is/are pending in the application.

4a) Of the above claim(s) *24-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the office action of 18 June 2003 and amendment submitted 17 September 2003 are acknowledged. Applicant's amendment and remarks are persuasive to remove the rejections under 35 USC 112 and 102 in the previous office action.

This application contains claims 24-60 drawn to an invention nonelected without traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (USPN 3,934,013).

Poulsen (USPN 3,934,013) discloses a topical pharmaceutical composition comprising a solvent base comprising 77.99% of propylene glycol/water and other excipients and adjuvants,

and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, see col. 11, lines 44-60, see also col. 10, CREAM BASE, for example.

Poulsen (USPN 3,934,013) does not teach some of the particular percentages of corticosteroid or propylene glycol herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ corticosteroid and propylene glycol in the particular weight percentages claimed herein.

One of ordinary skill in the art would have been motivated to employ corticosteroid and propylene glycol in the particular weight percentages claimed herein because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

Claims 8-9, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (USPN 3,934,013) as applied to claims 1-7 and 10, 13-19 above, and further in view of PDR entries of Lidex-Synalar.

Poulsen (USPN 3,934,013) does not teach the employment of a second penetration enhancer, neither does it teach the particular excipients herein as recited in claims 21-23.

PDR entries of Lidex-Synalar teaches the employment of propylene glycol and diisopropyl adipate together in a topical fluocinonide composition. PDR also teaches different excipients and adjuvants that can be employed in a topical fluocinonide composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any known pharmaceutical necessity in the amounts herein in a fluocinonide composition.

One of ordinary skill in the art would have been motivated to employ any known pharmaceutical necessity in the amounts herein in a fluocinonide composition because optimization of amounts is within the skill of the artisan and is therefore obvious.

Response to Arguments

Applicant's arguments filed 17 September 2003 have been fully considered but they are not persuasive. Applicant first argues that Poulsen does not teach or suggest a ratio of penetration enhancers to penetration enhancers, solvents and emulsifiers. As set forth on page 4 of the Office Action, Poulsen teaches that the preferred weight percentage of water/glycol mixture of the base is between 70-95%, see Office Action page 4, lines 1-2. This means that the weight percentage of all other excipients and the active is between 5-30%. Note that if the glycol mixture is 95% of the weight of the entire composition, it must be at least satisfy the 0.9 weight ratio of penetration enhancers to penetration enhancers, solvents and emulsifiers claimed herein.

Referring to Table 2, applicant avers unexpected results residing in different weight ratios of penetration enhancers to the sum of penetration enhancers, emulsifiers and solvents. Note that the data in Table 2 is not clear and convincing, note for example the average of summed vasoconstrictor scores of 0.089-0-80 and 0.679-0.70. Note that they are respectively 71 and 72. There does not seem to be a statistical difference among these two numbers. Also note that the standard deviation for these calculations is not provided. It is not clear why the applicant states that the vasoconstrictor score is "unexpectedly high".

Arguing against the second prior art reference, applicant states that PDR does not teach 0.90 wt ratio claimed herein. Note as discussed above Poulsen does indeed teach this limitation. Note further that the optimization of result effective parameters, i.e., amounts is within the skill of the artisan and is therefore obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
November 18, 2003

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER
12/1/03